



Docket No. 67694-A/JPW/GJG//MML/SK

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Jeffrey Sterling et al.

Serial No. : 10/718,879

Filed : November 20, 2003

For : PROPARGYL-TRIFLUOROMETHOXY-AMINO-BENZOTHIAZOLE DERIVATIVES

1185 Avenue of the Americas
New York, New York 10036
August 17, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants direct the Examiner's attention to the following documents which are listed on Form PTO-1449 (**Exhibit A**) and are also listed below.

Pursuant to the Notice appearing in the August 5, 2003 Official Gazette, because this application was filed after June 30, 2003, copies of the U.S. Patents and U.S. Patent Application Publications listed herein are not provided.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b) before the mailing of a first Office Action on the merits. Thus, this Information Disclosure Statement should be entered and considered. Copies of the

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documents listed below as items 8-13 and 5-28 are attached hereto as **Exhibits 1-20**. A copy of item 14 will be forwarded in due course.

Item 2 below was cited in a May 27, 2004 International Search Report issued in connection with PCT International Application No. PCT/US03/37592 which is related to the subject application. A copy of the International Search Report is enclosed as **Exhibit B**.

1. U.S. Patent No. 2,822,359, issued February 4, 1958 to Straley et al.;
2. U.S. Patent No. 4,535,088, issued August 13, 1985 to Makisumi, et al.;
3. U.S. Patent No. 4,826,860, issued May 2, 1989 to Johnson, et al.;
4. U.S. Patent No. 4,918,090, issued April 17, 1990 to Johnson, et al.;
5. U.S. Patent No. 4,971,983, issued November 20, 1990 to Johnson, et al.;
6. U.S. Patent No. 5,453,446, issued September 26, 1995 to Youdim, et al.;

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7. U.S. Patent No. 5,744,500, issued April 28, 1998 to Youdim, et al.;
8. Switzerland Patent No. 667091 A5, filed by Tabacchi et al., publication date September 15, 1988 (**Exhibit 1**);
9. European Patent Application No. EP 282 971 filed by Johnson et al., published on September 21, 1988 (**Exhibit 2**);
10. PCT International Publication No. WO 00/74676 published December 14, 2000 (**Exhibit 3**);
11. PCT International Publication No. WO 01/95907 published December 20, 2001 (**Exhibit 4**);
12. PCT International Application No. PCT/US03/5871 filed February 27, 2003, International Publication No. WO 2003/072055 A3 published September 4, 2003 (**Exhibit 5**);
13. PCT International Publication No. WO 2004/047756 published June 10, 2004 (**Exhibit 6**);
14. Barnett C.J. and J.C. Smirz. (1974) Organic Pre. Proc. Int., 6(4):179-82;

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15. Ben Simon et al. (1994) "A Controlled Trial of Riluzole in Amyotrophic Lateral Sclerosis." New Engl. J. Med., 330:585-91 (**Exhibit 7**);
16. Berge et al. (1977) "Pharmaceutical Salts." J. Pharm. Sci., 66:1-19 (**Exhibit 8**);
17. Domino, E.F. et al. (1952) "Pharmacological properties of benzazoles. I. Relationship between structure and paralyzing action." J. Pharmacol. Exp. Ther., 105: 486-97 (**Exhibit 9**);
18. Dreikorn, B.A. and Unger, P. (1989) J. Heterocyclic Chem.; 26:1735-7 (**Exhibit 10**);
19. Haley T.J and McCormick W.G. (1957) "Pharmacological effects produced by intracerebral injection of drugs in the conscious mouse." Brit. J. Pharmacol., 12:12-5 (**Exhibit 11**);
20. Jimonet, P. et al. (1999) "Riluzole series. Synthesis and in vivo "antiglutamate" activity of 6-substituted-2-benzothiazolamines and 3-substituted-2-imino-benzothiazolines." J. Med. Chem., 42:2828-3 (**Exhibit 12**);
21. Kalkers, N.F. et al. (2002) "The effect of the neuroprotective agent riluzole on MRI parameters in

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primary progressive multiple sclerosis: a pilot study."
Mult. Scler., 8:532-3 (**Exhibit 13**);

22. Katritzky, K.R. et al. (1987) "N-monomethylation of primary amines via intermediate benzothiazol-2(3H)-imines." J. Chem. Soc., Perkin Trans. I, 2539-41 (**Exhibit 14**);
23. The MERCK Index, 12th Edition, p.1416 (1996) MERCK & Co. Inc. (**Exhibit 15**);
24. The MERCK Manual, 17th Edition, Section 14, Chapter 180 (1999) MERCK & Co. Inc. (**Exhibit 16**);
25. Naoi, M. et al. (2002) "Mitochondria determine the survival and death in apoptosis by an endogenous neurotoxin, N-methyl(R)salsolinol, and neuroprotection by propargylamines." J. Neural Transmission, 109:607-721 (**Exhibit 17**);
26. Sasaki et al., (1998) "Advanced glycation end products in Alzheimer's disease and other neurodegenerative diseases." Am. J. Pathol., 153:1149-55 (**Exhibit 18**);
27. Tisch, R and McDevitt, HO. (1994) "Antigen-Specific Immunotherapy: Is It a Real Possibility to Combat T-Cell-Mediated Autoimmunity?" Proc. Natl. Acad. Sci. U.S.A., 91:437-8 (**Exhibit 19**); and

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28. Youdim, M.B.H. and Weinstock M. (2001) "Molecular basis of neuroprotective activities of rasagiline and the anti-Alzheimer drug TV3326 [(N-propargyl-(3R)aminoindan-5-YL)-ethyl methyl carbamate]." Cell. Mol. Neurobiol., 21(6): 555-73 (**Exhibit 20**).

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

Pursuant to 37 C.F.R. §1.97(b), no fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any fee is required, authorization is hereby given to charge the amount of such fee to Deposit Account No. 03-3125.

Respectfully submitted,

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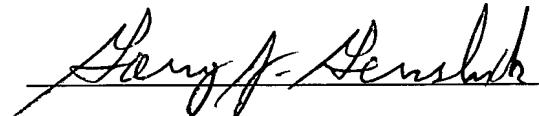
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28. Youdim, M.B.H. and Weinstock M. (2001) "Molecular basis of neuroprotective activities of rasagiline and the anti-Alzheimer drug TV3326 [(N-propargyl-(3R)aminoindan-5-YL)-ethyl methyl carbamate]." Cell. Mol. Neurobiol., 21(6): 555-73 (**Exhibit 20**).

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Respectfully submitted,

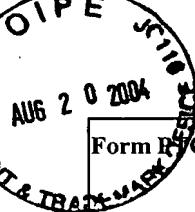


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Form PTO-1449

U.S. Department of Commerce
Patent and Trademark Office

Atty. Docket No. 67694-A/JPW/GJG/MML Serial No. 10/718,879

INFORMATION DISCLOSURE CITATION
(Use several sheets if necessary)

Applicants: Jeffrey Sterling, et al.

Filing Date November 20, 2003 Group

U.S. PATENT DOCUMENTS

Examiner Initial	Document Number						Date	Name	Class	Subclass	Filing Date if Appropriate
	2	8	2	2	3	5	9	2/4/58	Straley et al.;		
	4	5	3	5	0	8	8	8/13/85	Makisumi et al.;		
	4	8	2	6	8	6	0	5/2/89	Johnson et al.;		
	4	9	1	8	0	9	0	4/17/90	Johnson et al.;		
	4	9	7	1	9	8	3	11/20/90	Johnson et al.;		
	5	4	5	3	4	4	6	9/26/95	Youdim et al.;		
	5	7	4	4	5	0	0	4/28/98	Youdim et al.;		

FOREIGN PATENT DOCUMENTS

		Document Number	Date	Country	Class	Subclass	Translation		
							Yes	No	
SW	0	6	6	7	0	9	1	9/15/88	Switzerland;
EP	0	2	8	2	9	7	1	9/21/88	EPO;
WO	0	0	7	4	6	7	6	12/14/00	PCT;
WO	0	1	9	5	9	0	7	12/20/01	PCT;
WO	0	3	07	2	0	5	5	9/4/03	PCT;
WO	20	04	04	7	7	5	6	9/4/03	PCT;

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

Barnett C. J. and J. C. Smirz. (1974) <u>Organic. Prep. Proc. Int.</u> , 6(4):179-82;
Ben Simon et al. (1994) "A Controlled Trial of Riluzole in Amyotrophic Lateral Sclerosis." <u>New Engl. J. Med.</u> , 330:585-91;
Berge et al. (1977) "Pharmaceutical Salts." <u>J. Pharm. Sci.</u> , 66:1-19
Domino, E.F. et al. (1952) "Pharmacological properties of benzazoles. I. Relationship between structure and paralyzing action." <u>J. Pharmacol. Exp. Ther.</u> , 105: 486-97;
Dreikorn, B.A. and Unger, P. (1989) <u>J. Heterocyclic Chem.</u> , 26:1735-7
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EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Exhibit A